BILLING CODE 4120-01-P

#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

**Centers for Medicare & Medicaid Services** 

[CMS-9109-N]

Medicare and Medicaid Programs; Quarterly Listing of Program Issuances—January through March 2018

**AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.

**ACTION:** Notice.

**SUMMARY:** This quarterly notice lists CMS manual instructions, substantive and interpretive regulations, and other **Federal Register** notices that were published from January through March 2018, relating to the Medicare and Medicaid programs and other programs administered by CMS.

**FOR FURTHER INFORMATION CONTACT:** It is possible that an interested party may need specific information and not be able to determine from the listed information whether the issuance or regulation would fulfill that need. Consequently, we are providing contact persons to answer general questions concerning each of the addenda published in this notice.

Addenda	Contact	Phone Number
I CMS Manual Instructions	Ismael Torres	(410) 786-1864
II Regulation Documents Published in the Federal Register	Terri Plumb	(410) 786-4481
III CMS Rulings	Tiffany Lafferty	(410)786-7548
IV Medicare National Coverage Determinations	Wanda Belle, MPA	(410) 786-7491
V FDA-Approved Category B IDEs	John Manlove	(410) 786-6877
VI Collections of Information	William Parham	(410) 786-4669
VII Medicare –Approved Carotid Stent Facilities	Sarah Fulton, MHS	(410) 786-2749
VIII American College of Cardiology-National Cardiovascular Data Registry Sites	Sarah Fulton, MHS	(410) 786-2749
IX Medicare's Active Coverage-Related Guidance Documents	JoAnna Baldwin, MS	(410) 786-7205
X One-time Notices Regarding National Coverage Provisions	JoAnna Baldwin, MS	(410) 786-7205
XI National Oncologic Positron Emission Tomography Registry Sites	Stuart Caplan, RN, MAS	(410) 786-8564
XII Medicare-Approved Ventricular Assist Device (Destination Therapy) Facilities	Linda Gousis, JD	(410) 786-8616
XIII Medicare-Approved Lung Volume Reduction Surgery Facilities	Sarah Fulton, MHS	(410) 786-2749
XIV Medicare-Approved Bariatric Surgery Facilities	Sarah Fulton, MHS	(410) 786-2749
XV Fluorodeoxyglucose Positron Emission Tomography for Dementia Trials	Stuart Caplan, RN, MAS	(410) 786-8564
All Other Information	Annette Brewer	(410) 786-6580

#### I. Background

The Centers for Medicare & Medicaid Services (CMS) is responsible for administering the Medicare and Medicaid programs and coordination and oversight of private health insurance. Administration and oversight of these programs involves the following: (1) furnishing information to Medicare and Medicaid beneficiaries, health care providers, and the public; and (2) maintaining effective communications with CMS regional offices, state governments, state Medicaid agencies, state survey agencies, various providers of health care, all Medicare contractors that process claims and pay bills, National Association of Insurance Commissioners (NAIC), health insurers, and other stakeholders. To implement the various statutes on which the programs are based, we issue regulations under the authority granted to the Secretary of the Department of Health and Human Services under sections 1102, 1871, 1902, and related provisions of the Social Security Act (the Act) and Public Health Service Act. We also issue various manuals, memoranda, and statements necessary to administer and oversee the programs efficiently.

Section 1871(c) of the Act requires that we publish a list of all Medicare manual instructions, interpretive rules, statements of policy, and guidelines of general applicability not issued as regulations at least every 3 months in the **Federal Register**.

#### **II. Format for the Quarterly Issuance Notices**

This quarterly notice provides only the specific updates that have occurred in the 3-month period along with a hyperlink to the full listing that is available on the CMS website or the appropriate data registries that are used as our resources. This is the most current up-to-date information and will be available earlier than we publish our quarterly notice. We believe the website list provides more timely access for beneficiaries, providers, and suppliers. We also believe the website offers a more convenient tool for the public to find the full list of qualified

providers for these specific services and offers more flexibility and "real time" accessibility. In

addition, many of the websites have listservs; that is, the public can subscribe and receive

immediate notification of any updates to the website. These listservs avoid the need to check the

website, as notification of updates is automatic and sent to the subscriber as they occur. If

assessing a website proves to be difficult, the contact person listed can provide information.

III. How to Use the Notice

This notice is organized into 15 addenda so that a reader may access the subjects

published during the quarter covered by the notice to determine whether any are of particular

interest. We expect this notice to be used in concert with previously published notices. Those

unfamiliar with a description of our Medicare manuals should view the manuals at

http://www.cms.gov/manuals.

Dated: April 30, 2018.

Olen D. Clybourn,

Deputy Director,

Office of Strategic Operations and

Regulatory Affairs.

#### **Publication Dates for the Previous Four Quarterly Notices**

We publish this notice at the end of each quarter reflecting information released by CMS during the previous quarter. The publication dates of the previous four Quarterly Listing of Program Issuances notices are: May 5, 2017 (82 FR 21241), August 4, 2017 (82 FR 36404), October 27, 2017 (82 FR 49819) and January 26, 2018 (83 FR 3716). We are providing only the specific updates that have occurred in the 3-month period along with a hyperlink to the website to access this information and a contact person for questions or additional information.

## Addendum I: Medicare and Medicaid Manual Instructions (January through March 2018)

The CMS Manual System is used by CMS program components, partners, providers, contractors, Medicare Advantage organizations, and State Survey Agencies to administer CMS programs. It offers day-to-day operating instructions, policies, and procedures based on statutes and regulations, guidelines, models, and directives. In 2003, we transformed the CMS Program Manuals into a web user-friendly presentation and renamed it the CMS Online Manual System.

#### **How to Obtain Manuals**

The Internet-only Manuals (IOMs) are a replica of the Agency's official record copy. Paper-based manuals are CMS manuals that were officially released in hardcopy. The majority of these manuals were transferred into the Internet-only manual (IOM) or retired. Pub 15-1, Pub 15-2 and Pub 45 are exceptions to this rule and are still active paper-based manuals. The remaining paper-based manuals are for reference purposes only. If you notice policy contained in the paper-based manuals that was not transferred to the IOM, send a message via the CMS Feedback tool.

Those wishing to subscribe to old versions of CMS manuals should contact the National Technical Information Service, Department of Commerce, 5301 Shawnee Road, Alexandria, VA 22312 Telephone (703-605-6050). You can download copies of the listed material free of charge at: http://cms.gov/manuals.

#### How to Review Transmittals or Program Memoranda

Those wishing to review transmittals and program memoranda can access this information at a local Federal Depository Library (FDL). Under the FDL program, government publications are sent to approximately 1,400 designated libraries throughout the United States. Some FDLs may have

arrangements to transfer material to a local library not designated as an FDL. Contact any library to locate the nearest FDL. This information is available at http://www.gpo.gov/libraries/

In addition, individuals may contact regional depository libraries that receive and retain at least one copy of most federal government publications, either in printed or microfilm form, for use by the general public. These libraries provide reference services and interlibrary loans; however, they are not sales outlets. Individuals may obtain information about the location of the nearest regional depository library from any library. CMS publication and transmittal numbers are shown in the listing entitled Medicare and Medicaid Manual Instructions. To help FDLs locate the materials, use the CMS publication and transmittal numbers. For example, to find the manual for Healthcare Common Procedure Coding System (HCPCS) Codes Subject to and Excluded from Clinical Laboratory Improvement Amendments (CLIA) Edits, use (CMS-Pub. 100-04) Transmittal No. 3949.

Addendum I lists a unique CMS transmittal number for each instruction in our manuals or program memoranda and its subject number. A transmittal may consist of a single or multiple instruction(s). Often, it is necessary to use information in a transmittal in conjunction with information currently in the manual. For the purposes of this quarterly notice, we list only the specific updates to the list of manual instructions that have occurred in the 3-month period. This information is available on our website at www.cms.gov/Manuals.

Transmittal	Manual/Subject/Publication Number
Number	
	Medicare General Information (CMS-Pub. 100-01)
112	Issued to a specific audience, not posted to Internet/Intranet due to
	Confidentiality of Instruction
113	Issued to a specific audience, not posted to Internet/Intranet due to
	Confidentiality of Instruction
114	Internet Only Manual Updates to Pub. 100-01, 100-02 and 100-04 to Correct
	Errors and Omissions (SNF) (2018)
Medicare Benefit Policy (CMS-Pub. 100-02)	
239	Rural Health Clinic (RHC) and Federally Qualified Health Center (FQHC)
	Medicare Benefit Policy Manual Chapter 13 Update
240	Internet Only Manual (IOM) Update to Pub. 100-02, Chapter 11 - End Stage
	Renal Disease (ESRD), Section 100
241	New "K" Code for Therapeutic Shoe Inserts
	Therapeutic Shoes for Individual with Diabetes
242	Internet Only Manual Updates to Pub. 100-01, 100-02 and 100-04 to Correct
	Errors and Omissions (SNF) (2018)

Medicare National Coverage Determination (CMS-Pub. 100-03)	
204	Supervised Exercise Therapy (SET) for Symptomatic Peripheral Artery
	Disease (PAD)
205	Supervised Exercise Therapy (SET) for Symptomatic Peripheral Artery
	Disease (PAD)
20.45	Medicare Claims Processing (CMS-Pub. 100-04)
3945	New Waived Tests
3946	File Conversions Related to the Spanish Translation of the Healthcare
3947	Common Procedure Coding System (HCPCS) Descriptions  April 2018 Quarterly Average Sales Price (ASP) Medicare Part B Drug
3947	Pricing Files and Revisions to Prior Quarterly Pricing Files
3948	Ensuring Correct Processing of Home Health Disaster Related Claims and
3940	Claims for Denial No Payment Billing
3949	Healthcare Common Procedure Coding System (HCPCS) Codes Subject to
	and Excluded from Clinical Laboratory Improvement Amendments (CLIA)
	Edits
3950	2018 Durable Medical Equipment Prosthetics, Orthotics, and Supplies
	Healthcare Common Procedure Coding System (HCPCS) Code Jurisdiction
	List
3951	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity
	of Instruction
3952	Issued to a specific audience, not posted to Internet/Intranet due to a
	Confidentiality of Instruction
3953	Revisions to the Claims Processing for Grandfathered Oxygen Claims that
	Span Competitive Bidding Rounds Change in Suppliers for Oxygen and
	Oxygen Equipment
3954	Issued to a specific audience, not posted to Internet/Intranet due to a
2055	Confidentiality of Instruction
3955	Issued to a specific audience, not posted to Internet/Intranet due to a
3956	Confidentiality of Instruction  Issued to a specific audience, not posted to Internet/Intranet due to a
3930	Confidentiality of Instruction
3957	Issued to a specific audience, not posted to Internet/Intranet due to
3931	Confidentiality of Instruction
3958	Issued to a specific audience, not posted to Internet/Intranet due to a
3,30	Confidentiality of Instruction
3959	Issued to a specific audience, not posted to Internet/Intranet due to a
	Confidentiality of Instruction
3960	Issued to a specific audience, not posted to Internet/Intranet due to a
	Confidentiality of Instruction
3961	Editing Update for Mammography Services MSN Messages
	Remittance Advice Messages
3962	Modifications to the National Coordination of Benefits Agreement (COBA)
	Crossover Process
	Line-Item Modifiers Related to Reporting of Non-covered Charges When
	Covered and Non-covered Services Are on the Same Outpatient Claim
3963	Quarterly Update to the National Correct Coding Initiative (NCCI)
	Procedure-to-Procedure (PTP) Edits, Version 24.1, Effective April 1, 2018
3964	Issued to a specific audience, not posted to Internet/Intranet due to a

	Confidentiality of Instruction
3965	Reinstating the Qualified Medicare Beneficiary Indicator in the Medicare
	Fee-For-Service Claims Processing System from CR 9911
3966	Quarterly Healthcare Common Procedure Coding System (HCPCS)
	Drug/Biological Code Changes - April 2018 Update
3967	Issued to a specific audience, not posted to Internet/Intranet due to a
	Confidentiality of Instruction
3968	Consumer Friendly Spanish Descriptors for the Current Procedural
	Terminology (CPT) / Level 1 Healthcare Common Procedure Coding System
	(HCPCS) Codes and a Correction to the Part A Spanish Medicare Summary
	Notices (MSNs)
3969	Supervised Exercise Therapy (SET) for Symptomatic Peripheral Artery
	Disease (PAD)
3970	Removal of Contractor Reporting Requirements for the Physician Scarcity
	Area (PSA), the Health Professional Shortage Area Surgical Incentive
	Payment Program (HSIP) and the Primary Care Payment Incentive Program
	(PCIP) Quarterly Reports Reporting
3971	E/M Service Documentation Provided by Students (Manual Update)
	Evaluation and Management (E/M) Services
3972	Update to the Federally Qualified Health Center (FQHC) Prospective
	Payment System (PPS) for Calendar Year (CY) 2018 - Recurring File Update
3973	Quarterly Update for Clinical Laboratory Fee Schedule and Laboratory
	Services Subject to Reasonable Charge Payment
3974	Diagnosis Code Update for Add-on Payments for Blood Clotting Factor
	Payment for Blood Clotting Factor Administered to Hemophilia Inpatients
	Administered to Hemophilia Inpatients
3975	Healthcare Common Procedure Coding System (HCPCS) Codes Subject to
	and Excluded from Clinical Laboratory Improvement Amendments (CLIA)
2055	Edits
3976	Quarterly Update to the Medicare Physician Fee Schedule Database
2077	(MPFSDB) - April 2018 Update
3977	Healthcare Provider Taxonomy Codes (HPTCs) April 2018 Code Set Update
3978	Common Edits and Enhancements Modules (CEM) Code Set Update
3979	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity
2000	of Instruction
3980	Remittance Advice Remark Code (RARC), Claims Adjustment Reason Code
2001	(CARC), Medicare Remit Easy Print (MREP) and PC Print Update
3981	Issued to a specific audience, not posted to Internet/Intranet due to a
2002	Confidentiality of Instruction
3982	Update to the Federally Qualified Health Center (FQHC) Prospective
2002	Payment System (PPS) for Calendar Year (CY) 2018 - Recurring File Update
3983	Issued to a specific audience, not posted to Internet/Intranet due to a
2004	Confidentiality of Instruction
3984	Issued to a specific audience, not posted to Internet/Intranet due to a
2005	Confidentiality of Instruction
3985	Instructions for Downloading the Medicare ZIP Code File for July 2018
3986	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity
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3987	of Instruction Indian Health Services (IHS) Hospital Payment Rates for Calendar Year 2018

3988	April 2018 Update of the Hospital Outpatient Prospective Payment System (OPPS)
3989	April 2018 Integrated Outpatient Code Editor (I/OCE) Specifications Version 19.1
3990	Diagnosis Code Update for Add-on Payments for Blood Clotting Factor Administered to Hemophilia Inpatients
3991	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
3992	Supervised Exercise Therapy (SET) for Symptomatic Peripheral Artery Disease (PAD) General Billing Requirements Coding Requirements for SET Special Billing Requirements for Professional Claims Special Billing Requirements for Institutional Claims Common Working File (CWF) Requirements Applicable Medicare Summary Notice (MSN), Remittance Advice Remark Codes (RARC) and Claim Adjustment Reason Code (CARC) Messaging
3993	Reinstating the Qualified Medicare Beneficiary Indicator in the Medicare Fee-For-Service Claims Processing System from CR 9911 Qualified Medicare Beneficiary (QMB) Program
3994	April Quarterly Update for 2018 Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Fee Schedule
3995	Correction to Pub. 100-04, Chapter 5
3996	April 2018 Update of the Ambulatory Surgical Center (ASC) Payment System
3997	Quarterly Healthcare Common Procedure Coding System (HCPCS) Drug/Biological Code Changes - April 2018 Update
3998	File Conversions Related to the Spanish Translation of the Healthcare Common Procedure Coding System (HCPCS) Descriptions
3999	Quarterly Update for Clinical Laboratory Fee Schedule and Laboratory Services Subject to Reasonable Charge Payment
4000	Internet Only Manual Update to Pub 100-04, Chapter 16, Section 40.8 –Date of Service Policy Date of Service (DOS) for Clinical Laboratory and Pathology Specimens Internet Only Manual Updates to Pub. 100-01, 100-02 and 100-04 to Correct
	Errors and Omissions (SNF) (2018) Charges to Hold a Bed During SNF Absence Consolidated Billing Requirement for SNFs Furnishing Services that are Subject to SNF Consolidated Billing Under an "Arrangement" With an Outside Entity Other Excluded Services Beyond the Scope of a SNF Part A Benefit Dialysis and Dialysis Related Services to a Beneficiary With ESRD Other Services Excluded from SNF PPS and Consolidated Billing Ambulance Services Same Day Transfer Situations that Require a Discharge or Leave of Absence Determine Utilization on Day of Discharge, Death, or Day Beginning a
	Leave of Absence Leave of Absence Coverage Table for DME Claims

	Application of Limitation on Liability to SNF and Hospital Claims for
	Services Furnished in Noncertified or Inappropriately Certified Beds
	Determining Liability for Services Furnished in a Noncertified SNF or
	Hospital Bed
4002	Issued to a specific audience, not posted to Internet/Intranet due to
	Confidentiality of Instruction
4003	Issued to a specific audience, not posted to Internet/Intranet due to
	Confidentiality of Instruction
4004	April Quarterly Update for 2018 Durable Medical Equipment, Prosthetics,
	Orthotics and Supplies (DMEPOS) Fee Schedule
4005	April 2018 Update of the Hospital Outpatient Prospective Payment System
	(OPPS)
4006	April 2018 Integrated Outpatient Code Editor (I/OCE) Specifications Version
	19.1
4007	Consumer Friendly Spanish Descriptors for the Current Procedural
	Terminology (CPT) / Level 1 Healthcare Common Procedure Coding System
	(HCPCS) Codes and a Correction to the Part A Spanish Medicare Summary
	Notices (MSNs)
4008	Consumer Friendly Spanish Descriptors for the Current Procedural
	Terminology (CPT) / Level 1 Healthcare Common Procedure Coding System
	(HCPCS) Codes and a Correction to the Part A Spanish Medicare Summary
	Notices (MSNs)
4009	Update to the Internet Only Manual (IOM) Publication 100-04 - Medicare
	Claims Processing Manual, Chapter 27 - Contractor Instructions for Common
	Working File (CWF)
	General Information About the Common Working File (CWF) System
	Common Working File (CWF) Operations
	Communication between Host and MAC's Jurisdiction Sector Records
	received by the CWF Hosts
	Beneficiary Data Streamlining (BDS) Claims
	Adjustments/Cancels to Posted Claims
	Claim Maintenance Records
	Records received from the CWF Hosts
	BDS Basic Reply
	Claims Basic Reply
	Accepted (as is) for Payment
	Adjusted and Then Accepted for Payment
	Cancel/Void Claim Accepted
	Rejected
	Not in Host's File (NIF)
	Disposition Code 50 (Not in File)
	Disposition Code 51 (True Not in File on CMS Batch System)
	Disposition Code 52 (Beneficiary Record at Another)
	Disposition Code 53 (Record in CMS Alpha Match)
	Disposition Code 54 (Matched to Cross-referenced)
	Disposition Code 55 (Personal Characteristic Mismatch)
	Disposition Code 56 (MBI/HICN Mismatch)
	Claim Maintenance Records Basic Reply
	Unsolicited Response/Informational Unsolicited Response (UR/IUR)
	Reviewing the Beneficiary and Claim(s) Information

	Online Health Insurance Master Record (HIMR) Display
	CWF Provider Queries - Online Eligibility Information for Medicare Part A
	Providers
	Online Reporting (ORPT) System Display
	Requesting Assistance in Resolving CWF Utilization Problems
	Social Security Administration (SSA) Involvement
	Critical Case Procedure - Establishing Entitlement
	Referral of Critical Cases to the Regional Office
	Requesting or Providing Assistance to Resolve CWF Rejects
	Format for Requesting Assistance From Another A/B MAC or DME MAC
	on CWF Edits
	Paying Claims Outside of CWF
	Requesting to Pay Claims Outside of CWF
	Procedures for Paying Claims Outside of CWF
	Contractor Monthly Reports of Claims Paid Outside of CWF
	MAC Procedure
	Process Flow of a Change Request
	Handling Emergency Problems and Problems With Recent CWF Releases
	Distribution of "CWF Change Control" Reports
	Channels of Communication
	Schedule of CWF Software Releases
	Disposition Codes
	Error Codes
	Beneficiary Other Insurance Information (HUBO) Maintenance Transaction
	Error Codes
	Consolidated Claims Crossover Process
	Claims Crossover Disposition and Coordination of Benefits Agreement By-
	Pass Indicators
	Special Mass Adjustment and Other Adjustment Crossover Requirements
	Coordination of Benefits Agreement (COBA) Medigap Claim-Based
	Crossover Process
	Inclusion and Exclusion of Specified Categories of Adjustment Claims for
	Coordination of Benefits Agreement (COBA) Crossover Purposes
	Health Insurance Portability and Accountability Act (HIPAA) 5010 and
	National Council for Prescription Drug Programs (NCPDP) D.0 Crossover
	Requirements
4010	Revisions to Medicare Claims Processing Manual for End Stage Renal
	Disease
	Medicare Secondary Payer (CMS-Pub. 100-05)
	None
207	Medicare Financial Management (CMS-Pub. 100-06)
297	Notice of New Interest Rate for Medicare Overpayments and Underpayments
***	-2nd Qtr Notification for FY 2018
298	Removal of Contractor Reporting Requirements for the Physician Scarcity
	Area (PSA), the Health Professional Shortage Area Surgical Incentive
	Payment Program (HSIP) and the Primary Care Payment Incentive Program
	(PCIP) Quarterly Reports
299	Issued to a specific audience, not posted to Internet/Intranet due to
	Confidentiality of Instruction
300	The Fiscal Year 2018 Updates for the Centers for Medicare and Medicaid

	Services (CMS) Internet Only Manual (IOM) 100-06 The Medicare Financial
	Management Manual, Chapter 7 - Internal Control Requirements
	Federal Managers' Financial Integrity Act of 1982 (FMFIA)
	Control Activities
	CMS Contractor Internal Control Review Process and Timeline
	Risk Assessment
	Risk Analysis Chart
	Internal Control Objectives
	CMS Contractor Control Objectives
	Policies and Procedures
	Testing Methods
	Documentation and Working Papers
	Certification Package for Internal Controls (CPIC) Requirements
	OMB Circular A-123 Appendix A: Internal Controls Over Financial
	Reporting (ICOFR)
	Certification Statement
	CPIC- Report of Material Weaknesses
	CPIC - Report of Internal Control Deficiencies
	Material Weaknesses Identified During the Reporting Period
	Statement on Standards for Attestation Engagements (SSAE) Number 18,
	(SSAE 18) Reporting on Controls at Service Providers
	Submission, Review, and Approval of Corrective Action Plans
	Corrective Action Plan (CAP) Reports
	CMS Finding Numbers
	Initial CAP Report
	Quarterly CAP Report
	CMS CAP Report Template
	List of CMS Contractor Control Objectives
301	List of Commonly Used Acronyms  The Fiscal Year 2018 Updates for the Centers for Medicare and Medicaid
301	
	Services (CMS) Internet Only Manual (IOM) 100-06 The Medicare Financial
202	Management Manual, Chapter 7 - Internal Control Requirements
302	Removal of Contractor Reporting Requirements for the Physician Scarcity
	Area (PSA), the Health Professional Shortage Area Surgical Incentive
	Payment Program (HSIP) and the Primary Care Payment Incentive Program
	(PCIP) Quarterly Reports
177	Medicare State Operations Manual (CMS-Pub. 100-07)
177	Revisions to State Operations Manual (SOM) Appendix G, Guidance for
	Surveyors: Rural Health Clinics
7.62	Medicare Program Integrity (CMS-Pub. 100-08)
763	Issued to a specific audience, not posted to Internet/Intranet due to
764	Confidentiality of Instruction
764	Issued to a specific audience, not posted to Internet/Intranet due to
7.5	Confidentiality of Instruction
765	Medicare Diabetes Prevention Program (MDPP) Enrollment Process
	Definitions LP Color of the Col
	Licenses, Certifications, and Recognition
	Correspondence Address and E-mail Addresses
	Practice and Administrative Location Information
	Section 4 of the Form CMS-20134

Owning and Managing Organizations
Delegated Officials
Submission of Paper and Internet-based PECOS Certification Statements
Form CMS-855A, Form CMS-855B, and Form CMS-20134 Signatories
Supporting Documents
Supporting Documents for MDPP Suppliers - Recognition Status Timeliness
and Accuracy Standards
Standards for Initial and Revalidation Applications
Form CMS-855 and Form CMS-20134 Applications That Require a Site
Visit
Form CMS-855 and Form CMS-20134 Applications That Do Not Require a
Site Visit
Paper Applications - Accuracy
Web-Based Applications - Timeliness
Web-Based Applications That Require a Site Visit
Web-Based Applications That Do Not Require a Site Visit
Web-Based Applications - Accuracy
Standards for Changes of Information
Paper Applications - Timeliness
Paper Applications - Accuracy
Web-Based Applications - Timeliness
Web-Based Applications - Accuracy
General Timeliness Principles
Application Review and Verification Activities
Receipt/Review of Paper Applications
Verification of Data/Processing Alternatives
Processing Alternatives – Form CMS-20134 Paper Applications
Receiving Missing/Clarifying Data/Documentation Paper Applications
Internet-Based PECOS Applications Documentation
Special Program Integrity Procedures
Special Procedures for MDPP Suppliers
Special Processing Guidelines for Form CMS-855A, Form CMS-855B,
Form CMS-855I, and Form CMS-20134 Applications Returns
Rejections
Denials
Approval of Medicare Diabetes Prevention Program (MDPP) Suppliers
Changes of Information - General Procedures
Changes of Information and Complete Form CMS-855 and Form CMS-
20134 Applications
Incomplete or Unverifiable Changes of Information
Voluntary Terminations
Electronic Funds Transfers (EFT)
Existing or Delinquent Overpayments
Non-CMS-855 and Non-CMS-20134 Enrollment Activities
Contractor Communications
Internet-based PECOS Applications
Effective Date for MDPP Suppliers
Application Fees
Background
Scope of Site Visit
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	Changes of Information and Ownership Reactivations
	Site Verifications
	Provider Enrollment Inquiries
	Release of Information
	File Maintenance
	Model Revalidation Letters
	Model Revalidation Pend Letter
	Model Revalidation Deactivation Letter
	Model Revalidation Past-Due Group Member Letter
	Model Deactivation Letter due to Inactive Provider/Supplier Letter
	Model Return Revalidation Letter
	Model Approval Letter
	Denial Letter Guidance
	Denial Example #6 – MDPP Standards Not Met – Ineligible Coach Revocation Letter Guidance
	Revocation Example #3 – MDPP supplier Use of an Ineligible Coach Model Documentation Request Letter
	Reactivations - Deactivation for Reasons Other Than Non-Submission of a
	Claim
	Reactivations - Deactivation for Non-Submission of a Claim
	Reactivations- Miscellaneous Policies Revocations
	Other Identified Revocations
766	External Reporting Requirements
	Responsibility After Workload Transition
	Late Documentation Received by the CERT Review Contractor
	Administrative Relief to Damaged Areas from a Disaster
767	Issued to a specific audience, not posted to Internet/Intranet due to
	Confidentiality of Instruction
768	Post-Payment Review Timeliness Requirements
769	Issued to a specific audience, not posted to Internet/Intranet due to
	Confidentiality of Instruction
770	Issued to a specific audience, not posted to Internet/Intranet due to
	Confidentiality of Instruction
771	Clarification of Instructions Regarding the Intensive Level of Rehabilitation
	Therapy Services Requirements
	Medical Review of Inpatient Rehabilitation Facility (IRF) Services
	Reviewing for Intensive Level of Rehabilitation Therapy Services
	Requirements
772	Issued to a specific audience, not posted to Internet/Intranet due to
	Confidentiality of Instruction
773	Form CMS-8550 Processing Guide
774	Comprehensive Error Rate Testing (CERT) Program Dispute Process
	Disputing a CERT Decision
775	Issued to a specific audience, not posted to Internet/Intranet due to
	Confidentiality of Instruction
776	Issued to a specific audience, not posted to Internet/Intranet due to
	Confidentiality of Instruction
777	Issued to a specific audience, not posted to Internet/Intranet due to
	Confidentiality of Instruction
778	Updates to Payment Suspension Notice

8

779	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
780	Update to Exhibit 16 - Model Payment Suspension Letters in Pub. 100-08
	Payment Suspension Termination Notice
781	Issued to a specific audience, not posted to Internet/Intranet due to
	Confidentiality of Instruction
782	Update to Chapter 15 of Publication 100-08 - Medicare Enrollment
	Deactivation Policies
	Model Deactivation Letter
	Deactivation Revalidation Lists
	Mailing Revalidation Letters
	Large Group Revalidation Coordination
783	Proof of Delivery Exceptions for Immunosuppressant Drugs Paid Under the
, 05	Durable Medical Equipment (DME) Benefit Exceptions
784	Reviewing for Adverse Legal Actions (ALA)
	Final Adverse Action
	Reviewing for Adverse Legal Actions
Medicare	Contractor Beneficiary and Provider Communications (CMS-Pub. 100-09)
	None
N	Medicare Quality Improvement Organization (CMS- Pub. 100-10)
Madias	None are End Stage Renal Disease Network Organizations (CMS Pub 100-14)
Medica	None
Medi	icaid Program Integrity Disease Network Organizations (CMS Pub 100-15)
171041	None
	Medicare Managed Care (CMS-Pub. 100-16)
	None
N	Medicare Business Partners Systems Security (CMS-Pub. 100-17)
	None
	Demonstrations (CMS-Pub. 100-19)
190	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity
101	of Instruction
191	Update to CR9341 Oncology Care Model (OCM) Restricted Care
192	Management Code List  Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity
192	of Instruction
	One Time Notification (CMS-Pub. 100-20)
1996	Analyze Common Working File (CWF) System and Identify Layouts with
	Minimum FILLER Areas Available
1997	Enhancement to the Recovery Audit Contractor (RAC) Mass Adjustment
	Emancement to the Recovery Audit Contractor (RAC) Wass Adjustment
	Input File
1998	Input File HIGLAS Enhancement Required for Implementation of Overpayment based
	Input File HIGLAS Enhancement Required for Implementation of Overpayment based Denials
1999	Input File HIGLAS Enhancement Required for Implementation of Overpayment based Denials Implementation of the Transitional Drug Add-On Payment Adjustment
	Input File HIGLAS Enhancement Required for Implementation of Overpayment based Denials Implementation of the Transitional Drug Add-On Payment Adjustment MCS Proof of Concept to Convert Existing MCSDT Window to Utilize API
1999 2000	Input File HIGLAS Enhancement Required for Implementation of Overpayment based Denials Implementation of the Transitional Drug Add-On Payment Adjustment MCS Proof of Concept to Convert Existing MCSDT Window to Utilize API Technology
1999	Input File HIGLAS Enhancement Required for Implementation of Overpayment based Denials Implementation of the Transitional Drug Add-On Payment Adjustment MCS Proof of Concept to Convert Existing MCSDT Window to Utilize API

2002	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity of Instruction
2003	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity of Instruction
2004	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity of Instruction
2005	ICD-10 and Other Coding Revisions to National Coverage Determinations (NCDs)
2006	Monthly Status Report (MSR) Excel Data Template Updates and
2000	Implementation of MAC/CMS Data Exchange (MDX) Portal System
2007	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity of Instruction
2008	Shared System Enhancement 2015: Identify Inactive Medicare Demonstration Projects Within the Common Working File (CWF)
2009	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity of Instruction
2010	Analysis Only: Procedures to Handle Foreign (non US) Addresses
2011	Shared System Enhancement 2015: Identify Inactive Medicare Demonstration Codes 46, 48, and 49 within the Fiscal Intermediary Shared System (FISS)
2012	Analysis of Reject Responses for Prior Authorization/Pre-Claim Review
	Requests (PA/PCR) via the Electronic Submission of Medical Documentation
	(esMD) System and Usage of Standardized Review Reason Codes and
	Statements
2013	Global Surgical Days for Critical Access Hospital (CAH) Method II
2014	Identifying Prior Hospice Days When Calculating Hospice Routine Home
	Care Payments After a Transfer
2015	Updates to the Common Working File (CWF) to Allow Entry Code 9 Durable
	Medical Equipment (DME) Claims to Process Correctly
2016	Part B Detail Line Expansion – VMS
2017	Updates to Common Working File (CWF) Edits for Acute Kidney Injury (AKI) Claims
2018	Shared System Enhancement 2014: Implementation of Fiscal Intermediary
	Shared System (FISS) Obsolete Core Reports - Phase 2
2019	Redesign of Flu Vaccines in Fiscal Intermediary Shared System (FISS)
2020	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity of Instruction
2021	Shared System Enhancement 2014: Implementation of Fiscal Intermediary
	Shared System (FISS) Obsolete Financial Reports - Phase 2
2022	Modifications to the National Coordination of Benefits Agreement (COBA) Crossover Process
2023	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity
2023	of Instruction
2024	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity
2021	of Instruction
2025	Shared System Enhancement 2014: Implementation of Fiscal Intermediary
_0_0	Shared System (FISS) Obsolete On-Request Jobs - Phase 1
2026	Part B Detail Line Expansion - Multi-Carrier System (MCS) Phase 8
2027	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity
	of Instruction

2028	Shared System Enhancement 2014: Implementation of Fiscal Intermediary Shared System (FISS) Obsolete Financial Reports - Phase 3
2029	Implementation of Automating First Claim Review in Serial Claims for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)
2030	Shared System Enhancement 2014: Implementation of Fiscal Intermediary Shared System (FISS) Obsolete Core Reports - Phase 3
2031	Modifications to the Implementation of the Paperwork (PWK) Segment of the Electronic Submission of Medical Documentation (esMD) System
2032	Provider Enrollment, Chain, and Ownership System (PECOS) Extract Changes for Multi-Carrier System (MCS) - Analysis Only
2033	ICD-10 and Other Coding Revisions to National Coverage Determinations (NCDs)
2034	Identifying and Eliminating Discrepancies in Shared System Enrollment Data and Provider Enrollment Chain and Ownership System (PECOS) Data
2035	Targeted Probe and Educate Metrics Deliverables Update and Glossary
2036	Targeted Probe and Educate Metrics Deliverables Update and Glossary
2037	
	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity of Instruction
2038	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity of Instruction
2039	ICD-10 and Other Coding Revisions to National Coverage Determinations (NCDs)
2040	Appropriate Use Criteria for Advanced Diagnostic Imaging – Voluntary
	Participation and Reporting Period - Claims Processing Requirements – HCPCS Modifier QQ
2041	Redesign of Flu Vaccines in Fiscal Intermediary Shared System (FISS)
2042	Adjustments to Qualified Medicare Beneficiary (QMB) Claims Processed Under CR 9911
2043	The Supplemental Security Income (SSI)/Medicare Beneficiary Data for Fiscal Year 2016 for Inpatient Prospective Payment System (IPPS) Hospitals, Inpatient Rehabilitation Facilities (IRFs), and Long Term Care Hospitals (LTCH)
2044	National Correct Coding Initiative (NCCI) Add-on Codes for Non-Outpatient Prospective Payment System (OPPS) Institutional Providers Implementation
2045	
	Identifying and Eliminating Discrepancies in Shared System Enrollment Data and Provider Enrollment Chain and Ownership System (PECOS) Data
2046	Issued to a specific audience, not posted to Internet/ Intranet due to Sensitivity of Instruction
2047	Claims Processing Actions to Implement Certain Provisions of the Bipartisan Budget Act of 2018
2048	Fiscal Intermediary Shared System (FISS) Internal Crosswalk Modification
2049	National Supplier Clearinghouse (NSC) Numbers Shortage for Walgreen TIN
	licare Quality Reporting Incentive Programs (CMS- Pub. 100-22)
70	Issued to a specific audience, not posted to Internet/Intranet due to
, ,	Confidentiality of Instruction
71	Issued to a specific audience, not posted to Internet/Intranet due to
/ 1	
72	Confidentiality of Instruction
72	Issued to a specific audience, not posted to Internet/Intranet due to
	Confidentiality of Instruction

### Information Security Acceptable Risk Safeguards (CMS-Pub. 100-25) None

## Addendum II: Regulation Documents Published in the Federal Register (January through March 2018)

#### Regulations and Notices

Regulations and notices are published in the daily **Federal Register**. To purchase individual copies or subscribe to the **Federal Register**, contact GPO at www.gpo.gov/fdsys. When ordering individual copies, it is necessary to cite either the date of publication or the volume number and page number.

The **Federal Register** is available as an online database through GPO Access. The online database is updated by 6 a.m. each day the **Federal Register** is published. The database includes both text and graphics from Volume 59, Number 1 (January 2, 1994) through the present date and can be accessed at http://www.gpoaccess.gov/fr/index.html. The following website http://www.archives.gov/federal-register/ provides information on how to access electronic editions, printed editions, and reference copies.

This information is available on our website at: http://www.cms.gov/quarterlyproviderupdates/downloads/Regs-1Q18QPU.pdf

For questions or additional information, contact Terri Plumb (410-786-4481).

### Addendum III: CMS Rulings (January through March 2018)

CMS Rulings are decisions of the Administrator that serve as precedent final opinions and orders and statements of policy and interpretation. They provide clarification and interpretation of complex or ambiguous provisions of the law or regulations relating to Medicare, Medicaid, Utilization and Quality Control Peer Review, private health insurance, and related matters.

The rulings can be accessed at <a href="http://www.cms.gov/Regulations-and-Guidance/Guidance/Rulings">http://www.cms.gov/Regulations-and-Guidance/Guidance/Rulings</a>. For questions or additional information, contact Tiffany Lafferty (410-786-7548).

## Addendum IV: Medicare National Coverage Determinations (January through March 2018)

Addendum IV includes completed national coverage determinations (NCDs), or reconsiderations of completed NCDs, from the

quarter covered by this notice. Completed decisions are identified by the section of the NCD Manual (NCDM) in which the decision appears, the title, the date the publication was issued, and the effective date of the decision. An NCD is a determination by the Secretary for whether or not a particular item or service is covered nationally under the Medicare Program (title XVIII of the Act), but does not include a determination of the code, if any, that is assigned to a particular covered item or service, or payment determination for a particular covered item or service. The entries below include information concerning completed decisions, as well as sections on program and decision memoranda, which also announce decisions or, in some cases, explain why it was not appropriate to issue an NCD. Information on completed decisions as well as pending decisions has also been posted on the CMS website. For the purposes of this quarterly notice, we are providing only the specific updates that have occurred in the 3month period. This information is available at: www.cms.gov/medicarecoverage-database/. For questions or additional information, contact Wanda Belle, MPA (410-786-7491).

Title	NCDM Section	Transmittal Number	Issue Date	Effective Date
Supervised Exercise Therapy (SET) for Symptomatic Peripheral Artery	NCD 20.35	204	02/02/2018	05/25/2017

## Addendum V: FDA-Approved Category B Investigational Device Exemptions (IDEs) (January through March 2018)

Addendum V includes listings of the FDA-approved investigational device exemption (IDE) numbers that the FDA assigns. The listings are organized according to the categories to which the devices are assigned (that is, Category A or Category B), and identified by the IDE number. For the purposes of this quarterly notice, we list only the specific updates to the Category B IDEs as of the ending date of the period covered by this notice and a contact person for questions or additional information. For questions or additional information, contact John Manlove (410-786-6877).

Under the Food, Drug, and Cosmetic Act (21 U.S.C. 360c) devices fall into one of three classes. To assist CMS under this categorization process, the FDA assigns one of two categories to each FDA-approved investigational device exemption (IDE). Category A refers to experimental IDEs, and Category B refers to non-experimental IDEs. To obtain more

information about the classes or categories, please refer to the notice published in the April 21, 1997 **Federal Register** (62 FR 19328).

IDE	Device	Start Date
BB17905	CardiAMP CSCell Separator (BioCardia), Autologous Bone	01/26/2018
	Marrow Mononuclear Cells, Administered via Helix	
	Transendocardial Catheter	
BB17984	Transpose RT System	03/09/2018
BB17991	Safety and Efficacy of Injection of Adipose-Derived	03/09/2018
	Regenerative Cells (ADRCs)	
G150104	MAGFORCE USA,INC	02/09/2018
G170052	XACT Device	01/26/2018
G170203	Phil Embolic System	01/17/2018
G170265	DVisc40 OVD	02/15/2018
G170301	eCoin (Electroceutical Coin)	03/08//2018
G170304	e-OPRA Implant System	01/17/2018
G170309	Boston Scientific Precision Spectra Spinal Cord Stimulator	01/17/2018
	and CoverEdge 32 or X32 Surgical Leads	
G170312	Centralized Lung Evaluation System	01/26/2018
G170315	Model name: Mercury	01/26/2018
G180004	Tigertriever; Tigertriever 17	02/04/2018
G180005	Effectiveness of Repetitive Transcranial Stimulation (rTMS)	02/17/2018
	for the Improvement of Memory in Older Adults with	
	Traumatic Brain injury (TBI)	
G180007	Optune (NovoTTF 200A)	02/17/2018
G180011	Inpatient Safety and Feasibility Evaluation of the Zone-MPC	02/15/2018
	Control Algorithm Integrated into the APS APP	
G180015	enVista Multifocal (Trifocal) Intraocular Lens	02/24/2018
G180017	RxSight Light Adjustable Lens (RxLAL); Light Delivery	02/28/2018
	Device; Insestion Device - Cartridge; Insertion Device -	
	Injector Handle	
G180018	Optune - NovoTTF-200A System	02/28/2018
G180020	V-Wave Interatrial Shunt System	03/02/2018
G180021	RADIESSE (+) Lidocaine 1.5cc	03/07/2018
G180023	QuantiFERON-CMV	03/09/2018
G180026	e-OPRA Implant System	03/04/2018
G180027	aerFree (cNEP) AMS device	03/28/2018
G180030	Atom 0.5 Continuous Glucose Monitoring System, G6 Orion	03/16/2018
	Continuous Glucose Monitoring System	
G180031	The Novo TTF-200A System	03/18/2018
G180034	Water Jet Model ERBEJET 2 System with HybridAPC Probe	03/22/2018
G180035	Obalon Balloon System with Navigation and Touch	03/23/2018
G180037	BreathID MCS	03/27/2018
G180041	Optilume Drug Coated Balloon (DCB) Catheter	03/30/2018
G180044	Next-Generation TECNIS Symfony Extended Range of	03/30/2018
	Vision IOL	

### Addendum VI: Approval Numbers for Collections of Information (January through March 2018)

All approval numbers are available to the public at Reginfo.gov. Under the review process, approved information collection requests are assigned OMB control numbers. A single control number may apply to several related information collections. This information is available at www.reginfo.gov/public/do/PRAMain. For questions or additional information, contact William Parham (410-786-4669).

#### Addendum VII: Medicare-Approved Carotid Stent Facilities, (January through March 2018)

Addendum VII includes listings of Medicare-approved carotid stent facilities. All facilities listed meet CMS standards for performing carotid artery stenting for high risk patients. On March 17, 2005, we issued our decision memorandum on carotid artery stenting. We determined that carotid artery stenting with embolic protection is reasonable and necessary only if performed in facilities that have been determined to be competent in performing the evaluation, procedure, and follow-up necessary to ensure optimal patient outcomes. We have created a list of minimum standards for facilities modeled in part on professional society statements on competency. All facilities must at least meet our standards in order to receive coverage for carotid artery stenting for high risk patients. For the purposes of this quarterly notice, we are providing only the specific updates that have occurred in the 3-month period. This information is available at: http://www.cms.gov/MedicareApprovedFacilitie/CASF/list.asp#TopOfPage For questions or additional information, contact Sarah Fulton, MHS (410-786-2749).

Facility	Provider	Effective Date	State
	Number		
The following facilities	es are new listings fo	or this quarter.	
Aultman Hospital	1356376131	01/03/2018	OH
2600 Sixth Street S.W.			
Canton, OH 44710			
Lake Charles Memorial Hospital	1972549855	01/23/2018	LA
1701 Oak Park Boulevard			
Lake Charles, LA 70601			
Saint Thomas Midtown Hospital	440113	02/08/2018	TN
2000 Church Street			
Nashville, TN 37236			
West Hills Hospital & Medical	1023065729	03/20/2018	CA
Center			
7300 Medical Center Drive			

Facility	Provider Number	Effective Date	State
West Hills, CA 91307	rumber		
The following faciliti	es have editorial c	hanges (in hold)	
FROM: Franciscan St. Anthony	171005194	07/06/2006	IN
Health – Michigan City	171003194	07/00/2000	111
TO: Franciscan Health Michigan			
City			
301 West Homer Street			
Michigan City, IN 46360			
FROM: Franciscan Physicians	1427493246	12/03/2008	IN
Hospital	142/4/3240	12/03/2000	111
TO: Franciscan Health Munster			
701 Superior Avenue			
Munster, IN 46321			
FROM: Mercy Health Center	370013	04/12/2005	OK
TO: Mercy Hospital Oklahoma	3/0013	04/12/2003	OK
City 4300 W. Memorial Rd			
Oklahoma City, OK 73120	180130	06/14/2005	KY
FROM: Baptist Hospital East	180130	06/14/2005	Kĭ
TO: Baptist Health Louisville			
4000 Kresge Way			
Louisville, KY 40207	120002	0.5/4.4/2005	
FROM: Tenet Health System	420002	06/14/2005	SC
TO:Amisub of South Carolina,			
Inc.			
222 South Herlong Avenue			
Rock Hill, SC 29732			
D/B/A Piedmont Medical Center	100025	0.4/0.5/0.005	****
FROM: St. Elizabeth Medical	180035	04/26/2005	KY
Center South Unit			
TO: St. Elizabeth Healthcare			
Edgewood			
1 Medical Village Drive			
Edgewood, KY 41017	100015	111001000	
FROM: St. Elizabeth Florence	180045	11/03/2005	KY
TO: St. Elizabeth Healthcare			
Florence			
4900 Houston Road			
Florence, KY 41042	1		
FROM: United Hospital System,	520021	12/21/2007	WI
Inc.			
TO: Froedtert South Inc.			
6308 Eighth Avenue			
Kenosha, WI 53143-5082			
Dba Kenosha Medical Center and			
St. Catherine's Medical Center			

#### **Addendum VIII:**

#### American College of Cardiology's National Cardiovascular Data Registry Sites (January through March 2018)

Addendum VIII includes a list of the American College of Cardiology's National Cardiovascular Data Registry Sites. We cover implantable cardioverter defibrillators (ICDs) for certain clinical indications, as long as information about the procedures is reported to a central registry. Detailed descriptions of the covered indications are available in the NCD. In January 2005, CMS established the ICD Abstraction Tool through the Quality Network Exchange (QNet) as a temporary data collection mechanism. On October 27, 2005, CMS announced that the American College of Cardiology's National Cardiovascular Data Registry (ACC-NCDR) ICD Registry satisfies the data reporting requirements in the NCD. Hospitals needed to transition to the ACC-NCDR ICD Registry by April 2006.

Effective January 27, 2005, to obtain reimbursement, Medicare NCD policy requires that providers implanting ICDs for primary prevention clinical indications (that is, patients without a history of cardiac arrest or spontaneous arrhythmia) report data on each primary prevention ICD procedure. Details of the clinical indications that are covered by Medicare and their respective data reporting requirements are available in the Medicare NCD Manual, which is on the CMS website at <a href="http://www.cms.hhs.gov/Manuals/IOM/itemdetail.asp?filterType=none&filterByDID=99&sortByDID=1&sortOrder=ascending&itemID=CMS014961">http://www.cms.hhs.gov/Manuals/IOM/itemdetail.asp?filterType=none&filterByDID=99&sortByDID=1&sortOrder=ascending&itemID=CMS014961</a>

A provider can use either of two mechanisms to satisfy the data reporting requirement. Patients may be enrolled either in an Investigational Device Exemption trial studying ICDs as identified by the FDA or in the ACC-NCDR ICD registry. Therefore, for a beneficiary to receive a Medicare-covered ICD implantation for primary prevention, the beneficiary must receive the scan in a facility that participates in the ACC-NCDR ICD registry. The entire list of facilities that participate in the ACC-NCDR ICD registry can be found at www.ncdr.com/webncdr/common

For the purposes of this quarterly notice, we are providing only the specific updates that have occurred in the 3-month period. This information is available by accessing our website and clicking on the link for the

American College of Cardiology's National Cardiovascular Data Registry at: www.ncdr.com/webncdr/common. For questions or additional information, contact Sarah Fulton, MHS (410-786-2749).

Facility	City	State
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Facility	City	State
The following facilities are new	v listings for this quarter	•
Wayne Memorial Hospital	Honesdale	PA
Colquitt Regional Medical Center	Moultrie	GA
Roger Williams Medical Center	Providence	RI
Pinnacle Healthcare, LLC	Crown Point	IN
Peter Munk Cardiac Centre	Toronto	ON
Mount Sinai Hospital	Chicago	IL
WellStar North Fulton Hospital	Roswell	GA
Arcadia Outpatient Surgery Center, LP	Arcadia	CA
St. Francis Medical Center	Colorado Springs	CO
Avita Ontario Hospital	Ontario	OH
J.C. Blair Memorial Hospital	Huntingdon	PA
Providence Medford Medical Center	Medford	OR
Tristar Horizon Medical Center	Dickson	TN

## Addendum IX: Active CMS Coverage-Related Guidance Documents (January through March 2018)

CMS issued a guidance document on November 20, 2014 titled "Guidance for the Public, Industry, and CMS Staff: Coverage with Evidence Development Document". Although CMS has several policy vehicles relating to evidence development activities including the investigational device exemption (IDE), the clinical trial policy, national coverage determinations and local coverage determinations, this guidance document is principally intended to help the public understand CMS's implementation of coverage with evidence development (CED) through the national coverage determination process. The document is available at http://www.cms.gov/medicare-coverage-database/details/medicare-coverage-document-details.aspx?MCDId=27. There are no additional Active CMS Coverage-Related Guidance Documents for the 3-month period. For questions or additional information, contact JoAnna Baldwin, MS (410-786-7205).

#### Addendum X:

#### List of Special One-Time Notices Regarding National Coverage Provisions (January through March 2018)

There were no special one-time notices regarding national coverage provisions published in the 3-month period. This information is available at www.cms.hhs.gov/coverage. For questions or additional information, contact JoAnna Baldwin, MS (410-786 7205).

### Addendum XI: National Oncologic PET Registry (NOPR) (January through March 2018)

Addendum XI includes a listing of National Oncologic Positron Emission Tomography Registry (NOPR) sites. We cover positron emission tomography (PET) scans for particular oncologic indications when they are performed in a facility that participates in the NOPR.

In January 2005, we issued our decision memorandum on **positron emission tomography** (PET) scans, which stated that CMS would cover PET scans for particular oncologic indications, as long as they were performed in the context of a clinical study. We have since recognized the National Oncologic PET Registry as one of these clinical studies. Therefore, in order for a beneficiary to receive a Medicare-covered PET scan, the beneficiary must receive the scan in a facility that participates in the registry. There were no additions, deletions, or editorial changes to the listing of National Oncologic Positron Emission Tomography Registry (NOPR) in the 3-month period. This information is available at http://www.cms.gov/MedicareApprovedFacilitie/NOPR/list.asp#TopOfPage. For questions or additional information, contact Stuart Caplan, RN, MAS (410-786-8564).

## Addendum XII: Medicare-Approved Ventricular Assist Device (Destination Therapy) Facilities (January through March 2018)

Addendum XII includes a listing of Medicare-approved facilities that receive coverage for ventricular assist devices (VADs) used as destination therapy. All facilities were required to meet our standards in order to receive coverage for VADs implanted as destination therapy. On October 1, 2003, we issued our decision memorandum on VADs for the clinical indication of destination therapy. We determined that VADs used as destination therapy are reasonable and necessary only if performed in facilities that have been determined to have the experience and infrastructure to ensure optimal patient outcomes. We established facility standards and an application process. All facilities were required to meet our standards in order to receive coverage for VADs implanted as destination therapy.

For the purposes of this quarterly notice, we are providing only the specific updates to the list of Medicare-approved facilities that meet our standards that have occurred in the 3-month period. This information is available at

http://www.cms.gov/MedicareApprovedFacilitie/VAD/list.asp#TopOfPage.

For questions or additional information, contact Linda Gousis, JD, (410-786-8616).

Facility	Provider Number	Date Approved	State
The following facilities are new listings for this quarter.			
CJW Medical Center –	490112	12/19/2017	VA
Johnston Willis Hospital			
1401 Johnston Willis Dr.			
Richmond, VA 23225			
Other Information:			
DNV-GL #252385-2017-VAD			
Wellstar Kennestone Hospital	110035	11/08/2017	GA
677 Church Street			
Marietta, GA 30060			
Other Information:			
Joint Commission # 6711	111/1 1 11/1 1 1		
	cilities have editorial char		TDX Z
FROM: Methodist Specialty	450388	08/09/2017	TX
and Transplant Hospital			
TO: Methodist Hospital			
7700 Floyd Curl Drive			
San Antonio, TX 78229			
Other Information:			
Joint Commission # 9219			
Barnes-Jewish Hospital	260032	11/11/2017	MO
1 Barnes Jewish Hospital	200032	11/11/2017	MO
Plaza			
Saint Louis, MO 63110			
Saint Louis, WO 03110			
Other Information:			
Joint Commission # 8387			
Riverside Methodist Hospital	360006	08/30/2017	OH
3535 Olentangy River Road		00,0012017	
Columbus, OH 43214			
Other Information:			
Joint Commission # 7030			
Lehigh Valley Hospital	390133	12/13/2017	PA
1200 S. Cedar Crest Boulevard			
Allentown, PA 18105			
Other Information:			
Joint Commission # 4880			

Facility	Provider Number	Date Approved	State
FROM: Christiana Care –	08-0001	10/25/2017	DE
Christiana Hospital			
TO: Christiana Hospital			
4755 Ogletown-Stanton Road			
Newark, DE 19718			
Other Information:			
Joint Commission # 6237			
University of California San	050025	10/18/2017	CA
Diego Medical			
200 West Arbor Drive			
San Diego, CA 92103			
Other Information:			
Joint Commission # 10071	1.40000	10/25/2015	**
FROM: University of	140088	10/25/2017	IL
Chicago Hospitals and Health			
System TO: University of Chicago			
Medical Center			
5841 South Maryland Avenue			
Chicago, IL 60637			
Chicago, IL 00037			
Other Information:			
Joint Commission # 7315			
Keck Hospital of USC	050696	10/21/2017	CA
1500 San Pablo Street	030070	10/21/2017	011
Los Angeles, CA 90033			
<i>g, 1</i>			
Other Information:			
Joint Commission # 5033			
FROM: Sutter Memorial	050108	11/08/2017	CA
Hospital			
TO: Sutter Medical Center			
2825 Capitol Avenue			
Sacramento, CA 95816			
Other Information:			
Joint Commission # 2902	400112	12/10/2017	77.4
FROM: CJW Medical Center	490112	12/19/2017	VA
- Johnston Willis Hospital			
TO: CJW Medical Center –			
Chippenham Hospital 7101 Jahnke Road			
Richmond, VA 23225			
Other Information:			
DNV-GL #252385-2017-VAD			
New York-Presbyterian/Weill	33-0101	10/26/2017	NY
14CW 10IK-11esbyterian/Welli	33-0101	10/20/2017	111

Facility	Provider Number	Date Approved	State
Cornell Medical Center			
525 East 68th Street			
New York, NY, 10065			
Other Information:			
Joint Commission # 5838			
FROM: St Luke's Medical	520138	11/15/2017	WI
Center TO: Aurora St.			
Luke's Medical Center of			
Aurora Health Care Metro,			
Inc.			
2900 W Oklahoma Avenue			
Milwaukee, WI 53215			
Other Information:			
Joint Commission # 7675			
FROM: University of	180067/1518911338	12/06/2017	KY
Kentucky Health Care -			
Chandler Hospital			
TO: University of Kentucky			
Hospital/ UK Albert B.			
Chandler Hospital			
800 Rose Street			
Lexington, KY 40536			
Other Information:			
Joint Commission # 7760			
FROM: Jackson Memorial	100022	12/09/2017	FL
Hospital, University of Miami			
TO: Jackson Memorial			
Hospital			
1611 NW 12th Avenue			
Miami, FL 33136			
Other Information:			
Joint Commission # 6850			
Westchester Medical Center	330234	12/20/2017	NY
100 Woods Road			
Valhalla, NY 10595			
Other Information:			
Joint Commission # 2518			

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Facility	Provider Number	Date Approved	State
FROM: Morristown	310015	12/13/2017	NJ
Memorial Hospital			
TO: Morristown Medical			
Center			
100 Madison Avenue			
Morristown, NJ 07960			
Other Information:			
Joint Commission # 5958			
FROM: Ochsner Clinic	190036	12/13/2017	LA
Foundation TO: Ochsner			
Medical Center			
1514 Jefferson Highway			
New Orleans, LA 70121			
Other Information:			
Joint Commission # 8777			
FROM: Scott & White	450054	12/20/2017	TX
Memorial Hospital	430034	12/20/2017	11
TO: Scott & White Medical			
Center Vinte Wedicar			
2401 South 31st Street			
Temple, TX 76508			
Temple, 174 70500			
Other Information:			
Joint Commission # 9241			
University of Washington	500008	12/06/2017	WA
Medical Center	200000	12/00/2017	*****
1959 NE Pacific Street			
Seattle, WA 98195			
,			
Other Information:			
Joint Commission # 9626			
Mayo Clinic Hospital-	240010	03/24/2018	MN
Rochester		1	
1216 2nd St SW			
Rochester, MN 55902			
Other Information:			
Joint Commission # 8181			
University of Texas Medical	450018	01/31/2018	TX
301 University Boulevard			
Galveston, TX 77555			
Other Information:			
Joint Commission # 9058			

# Addendum XIII: Lung Volume Reduction Surgery (LVRS) (January through March 2018)

Addendum XIII includes a listing of Medicare-approved facilities that are eligible to receive coverage for lung volume reduction surgery. Until May 17, 2007, facilities that participated in the National Emphysema Treatment Trial were also eligible to receive coverage. The following three types of facilities are eligible for reimbursement for Lung Volume Reduction Surgery (LVRS):

- National Emphysema Treatment Trial (NETT) approved (Beginning 05/07/2007, these will no longer automatically qualify and can qualify only with the other programs);
- Credentialed by the Joint Commission (formerly, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO)) under their Disease Specific Certification Program for LVRS; and
  - Medicare approved for lung transplants.

Only the first two types are in the list. There were editorial updates to the listing of facilities for lung volume reduction surgery published in the 3-month period. This information is available at www.cms.gov/MedicareApprovedFacilitie/LVRS/list.asp#TopOfPage. For questions or additional information, contact Sarah Fulton, MHS (410-786-2749).

Facility	Provider Number	Date Approved	State
The following facilities have editorial changes (in bold).			
FROM: The Ohio State University	36-0085	10/29/2016	OH
Hospital			
TO: Ohio State University Hospitals			
410 West Tenth Avenue, DN 168			
Columbus, OH 43210			
Other Information:			
Joint Commission # 7029			
FROM: Temple University Hospital	39-0027	03/25/2017	PA
TO: Temple University Hospital,			
Inc.			
3401 North Broad Street			
Philadelphia, PA 19140			
Other Information:			
Joint Commission # 6152			

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Facility	Provider Number	Date Approved	State
Memorial Medical Center	14-0148	05/06/2017	IL
701 North First Street			
Springfield, IL 62781-0001			
Other Information:			
Joint Commission # 7431			

## Addendum XIV: Medicare-Approved Bariatric Surgery Facilities (January through March 2018)

Addendum XIV includes a listing of Medicare-approved facilities that meet minimum standards for facilities modeled in part on professional society statements on competency. All facilities must meet our standards in order to receive coverage for bariatric surgery procedures. On February 21, 2006, we issued our decision memorandum on bariatric surgery procedures. We determined that bariatric surgical procedures are reasonable and necessary for Medicare beneficiaries who have a body-mass index (BMI) greater than or equal to 35, have at least one co-morbidity related to obesity and have been previously unsuccessful with medical treatment for obesity. This decision also stipulated that covered bariatric surgery procedures are reasonable and necessary only when performed at facilities that are: (1) certified by the American College of Surgeons (ACS) as a Level 1 Bariatric [FR Doc. 2018-09430 Filed: 5/3/2018 8:45 am; Publication Date: 5/4/2018]

Surgery Center (program standards and requirements in effect on February 15, 2006); or (2) certified by the American Society for Bariatric Surgery (ASBS) as a Bariatric Surgery Center of Excellence (BSCOE) (program standards and requirements in effect on February 15, 2006).

There were no additions, deletions, or editorial changes to Medicare-approved facilities that meet CMS's minimum facility standards for bariatric surgery that have been certified by ACS and/or ASMBS in the 3-month period. This information is available at www.cms.gov/MedicareApprovedFacilitie/BSF/list.asp#TopOfPage. For questions or additional information, contact Sarah Fulton, MHS (410-786-2749).

## Addendum XV: FDG-PET for Dementia and Neurodegenerative Diseases Clinical Trials (January through March 2018)

There were no FDG-PET for Dementia and Neurodegenerative Diseases Clinical Trials published in the 3-month period.

This information is available on our website at www.cms.gov/MedicareApprovedFacilitie/PETDT/list.asp#TopOfPage. For questions or additional information, contact Stuart Caplan, RN, MAS (410-786-8564).